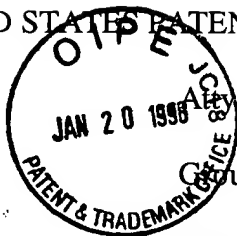


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: R. Rosenberger
Applicant(s): E. W. Stark
Serial No.: 08/818,289

Office Docket: 653.001US1
Group Art Unit 2505
Filed 03/14/97



#46/Declaration
2-4-98

Title: METHOD AND APPARATUS FOR OPTICAL INTERACTANCE AND TRANSMITTANCE MEASUREMENTS

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 CFR § 1.131

DEAR SIR:

I, Edward Stark, hereby declare the following:

I

I have been educated as a physicist and electrical engineer having received my Bachelor of Arts in Physics from Oberlin College in 1953, my Bachelor of Science in Electrical Engineering from the University of Illinois with University Honors in 1954, and my Master of Science in Electrical Engineering from the Polytechnic Institute of Brooklyn in 1958.

II

I co-founded and have been employed as Vice President for Research and Development by KES Analysis, Inc. since 1984 consulting in the field of near-infrared spectroscopy, and inventing, developing and licensing diode-array spectrophotometer technology, including the improved method and apparatus for optical interactance and transmittance measurements of the pending patent application. During this time four U.S. patents have been granted to me with two pending. In 1992 I co-founded and since have served as President of BioNIR, Inc. which is engaged in research and development of medical applications of this technology.

From 1970 through February 1985 I was employed by Technicon Instruments Corporation rising to Principal Scientist after holding positions of Vice President Systems Management in the Clinical Division and Vice President Research and Development in the Industrial Division. I am inventor and/or co-inventor on seven patents granted for this work.

I was employed from 1955 through 1970 by the Sperry Gyroscope division of the Sperry-Rand Corporation, performing research and development in the field of infrared detection and electro-optics, becoming Engineering Department Head in the Electro-Optics Group in June of 1965 and

Product Development Manager in October 1968. Ten patents were granted to myself and co-inventors.

III

During a period prior to December 15, 1989, I invented the multiple ring probe that is the subject of the pending patent application. I discussed this invention with Mr. Karl H. Norris, the originator of the interactance method of measuring the composition of materials. We traveled together to visit two fiber-optic equipment manufacturers, Fostek, Inc. and Volpi Manufacturing USA, both in Auburn, NY. On the plane, Mr. Norris and I discussed the geometry and methods of assembling such probes. The probes were then discussed in detail at Fostek and Volpi. Pages 1-9 of the attached sketches were made to illustrate discussions during this trip. In particular, pages 1 and 2 illustrate the concept of conical arrangements of the rings. Pages 3 to 6 provide preliminary dimensions and introduce the concept of ribbons of fibers as a means of construction. Pages 7 to 9 illustrate the concept of adding monitor fibers to the bundle.

Volpi Manufacturing responded with their quote no. 12110 dated prior to December 15, 1989 whose items correspond to the five numbered items on page 3 of the sketches referenced above as follows: Volpi items 1 and 2, sketch item 1; Volpi items 3 and 4, sketch item 1 with added monitor bundle; Volpi items 5 and 6, sketch item 2; Volpi item 7, sketch item 3; Volpi items 8 and 9, sketch item 4; and Volpi item 10, sketch item 5. These parts were designed so as to put together various combinations to evaluate configurations.

Fostek responded with their fax # 221 and then quote no. 1431 and drawing 1431.01 (2 sheets) for a multiple ring probe comprising 10 concentric illumination rings and a central receiver plus two additional receiver rings. The receivers are denoted A1, A2, and A3 on the drawing. The original configuration would require 414 mm² of fiber so Fostek proposed reduction of the active fiber density as shown in their fax #221 P02, on which I made contemporaneous pencil notes of desired corrections which are reflected in their quote no. 1431. This configuration encompasses both illumination surrounding detection and detection surrounding illumination.

Each and every one of these documents was created and in my possession prior to December 15, 1989. At least each set of documents, except for the nine pages of sketches referred to above and appended hereto, was dated at the time of creation and those dates remain on those sets of documents. Those sketches can be placed in time accurately as they were made at the time of a trip to Fostec and Volpi Manufacturing. The documents, at least in their composite, show a clear conception of the invention represented by claims 1, 6, and 7 of my U.S. Patent Application Serial No.: 08/818,289, as those claims appear in the Amendment filed contemporaneously with this declaration.

Drawing 1431.01 in the document received from Fostec, as described in detail above, shows the use of concentric circles of fiber optics for illumination interspersed with concentric circles of fiber optics for collection of radiation and a central core receiver. The document received from Volpi Manufacturing within a few weeks of the trip to Fostec and Volpi Manufacturing also shows a

diligent course of conduct in obtaining the materials to physically construct the device of claims 1, 6, and 7.

Shortly after conceiving this invention, and within one month after the Fostec and Volpi proposals, I entered into negotiations with a third party for funding to continue development of the near-infrared diode-array spectrophotometer system, including the probe of the subject invention. Use of a diode-array spectrophotometer as the detection system in conjunction with the probe is indicated on page 6 lines 13-14 of the specification. Completion of the diode array spectrophotometer was necessary before the probe could be tested, even though the construction of the probe could have been readily physically accomplished based upon the definitive conception evidenced by the documents. As the actual testing of the device could not be accomplished without completion of the diode array spectrophotometer, this task was given priority. The copy of the confidential disclosure agreement signed to facilitate negotiations is appended.

A proposal for "Investigation of Near-infrared Spectroscopy for Non-invasive Blood Glucose Monitoring and Other Medical Analyses" was submitted three weeks later. The multiple concentric ring probe was mentioned on page 14 and included in Appendix C -Instrument Specifications section 1.3.3. A copy of the cover sheet, the relevant portion of page 14, and page one of Appendix C are appended. All of this work was still performed prior to December 15, 1989, based upon dates on the documents themselves.

A preliminary agreement was signed within 3 months which provided interim funding. (2 pages appended). The final agreement was signed prior to December 15, 1989 incorporating within Appendix A -Technical Program Plan "7. Development of optical probes" including "..., the multiple source/receiver geometry..." The first page, signature page, and page A-3 of the technical program plan are appended.

Diligence in pursuing this development program is evidenced by the R&D expenses listed on from page 9 thru the top of page 15 of the KES Analysis, Inc. 1989 General Ledger and pages 10 and 11 of the KES Analysis, Inc. 1990 General Ledger (Copies appended). A typical early drawing for the spectrophotometer drawn by D. Landon, dated prior to December 15, 1989, and titled "Slit -Dwg No KES 1011-* -A" is appended. Some of these drawings were updated in March 1990, for example "Single Detector Cover -Dwg No. KES 1018A" which is appended. The dates clearly provided in the first column on the left-hand side of the pages of the General Ledger (both 1989 and 1990) show diligence in the performance of work on the probe system of this invention. The dates show payment dates for individual orders of parts for the reduction to practice of the system, with nearly weekly dates from November of 1989 through the order date for final assembly of the probe device on June 5, 1990. This is clear evidence of diligent work from conception prior to December 15, 1989 through actual reduction to practice in August of 1990.

While the necessary diode-array spectrometer development was proceeding, consideration of probe designs continued as documented by the Fostec drawings 1832 dated 2/18/90 and quotation 1832.01

dated 2/19/90. Solely due to the complexity and expense of the original multiple ring configuration, I simplified the design as shown in my drawings of 5/17/90 and 5/22/90 (copies appended). Based on my drawings, Fostec revised its quotation 1832.01 as 1942.01. I placed P.O. 1170 (purchase order) for two of these probes on 6/5/90. Fostec prepared drawing 1942.01 on 6/15/90 and shipped the dual ring probes on 8/27/90. Copies of this quotation, drawing and the Fostec shipping document, which also includes the date entered and KES PO number, are appended.

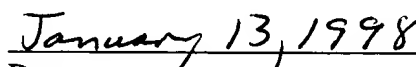
As is noted on quotations (e.g., the Fostec quotations of February 19, 1990 and May 22, 1990), delivery of ordered materials was estimated at about six weeks or six to eight weeks, even with specified designs, so that continuous work could not be performed as materials had to be waited for over such extended periods. As these events were outside my ability to control, these time intervals were a necessary part of development and were consistent with diligence in the reduction to practice of the invention after conception. In fact, upon placing the definitive order on June 5, 1990 for the construction of the probe, which could then be used with the constructed diode array, the assembled probe was not delivered until August 27, 1990, more than eleven weeks later.

Based on the above chronology, it is my belief that physical reduction to practice was pursued diligently from conception. Evaluation of the multiple path probe depended on availability of the diode-array spectrophotometer. The first diode-array spectrophotometer was delivered on April 9, 1990 (delivery receipt signed April 22, 1990 appended) which provided the basis for final design of the dual-ring probe. Within a month, I completed the design and I placed the purchase order within two weeks thereafter, effecting the first physical reduction to practice of the invention covered in my U.S. Patent Application Serial No.: 08/818,289.

I, Edward Stark, hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Signature of Declarant



Date